IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Boyd et al.	)	Examiner: Pedro Philogene
Application No.: 10/667,540	)	Group: 3733
Filed: October 29, 2002	)	Confirmation No.: 9957
DEVICES AND METHODS FOR THE RESTORATION OF A SPINAL DISC	)	

DECLARATION UNDER 37 C.F.R. 1.131

I , Lawrence M. Boyd, hereby state as follows:

1. I am a named inventor, along with Maureen Upton, on U.S. Patent application S.N. 10/667,540, which claims priority to two provisional applications filed on November 1, 2001, for which I am also a named inventor, namely No. 60/336,002, entitled "Devices, Methods and Assemblies for Intervertebral Disc Repair and Regeneration," and No. 60/336,332, entitled "Pretreatment of Cartilaginous Endplates Prior to Treat of the Intervertebral Disc with an Injectable Biomaterial."

2. At least prior to July 30, 2001, we conceived a kit of parts for sealably introducing fluent material directly into the disc space through an opening extending through the annulus fibrosis of the disc, comprising: (i) a tube having a passageway for the flow of fluent material therethrough and an extent adapted to be received in the opening of the annulus fibrosis, the tube having a seal adapted to engage the annulus fibrosis adjacent the opening and to form a fluid-tight seal therewith, wherein the tube extent is defined by a distal tip of the tube, the distal tip being sized and configured to provide distraction of opposed vertebrae communicating with the disc space, and (ii) a quantity of curable fluent material adapted to be introduced in a fluid state into the disc space through the passageway of the tube, the material upon curing having properties substitutive of the nucleus pulposus, all as defined in at least claim 85 of the present application S.N. 10/667,540.

3. Prior to July 30, 2001, I prepared a confidential presentation, attached hereto as Exhibit A, which included drawings and written material that described the kit of parts that we had conceived. Exhibit A is a true and authentic copy of that confidential presentation, except with the dates redacted.

4. For the period from July 30, 2001, to the date on which the above-identified provisional applications were filed (November 1, 2001), I diligently pursued the constructive reduction to practice of the invention embodied in those provisional applications, including the kit of parts described above. In particular, for the period from July 30, 2001, until November 1, 2001, I continued to refine certain aspects my invention, and worked with patent counsel on the preparation and filing of the provisional application No. 60/336,002. In particular, as reflected in the documents attached hereto as Exhibit B, I provided information to patent counsel and reviewed drafts of the application in preparation for filing. Exhibit B is a true and authentic copy of the identified documents, with the dates and certain confidential material redacted. The patent counsel was reasonably diligent in providing drafts and incorporating my changes up to the final filing of the provisional application on November 1, 2001.

5. I believe that all of the statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements have been made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the present application of any patent that may issue thereon

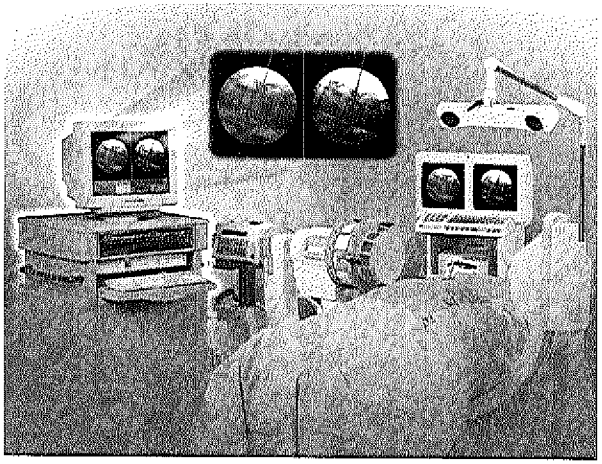
Lawrence M. Boyd

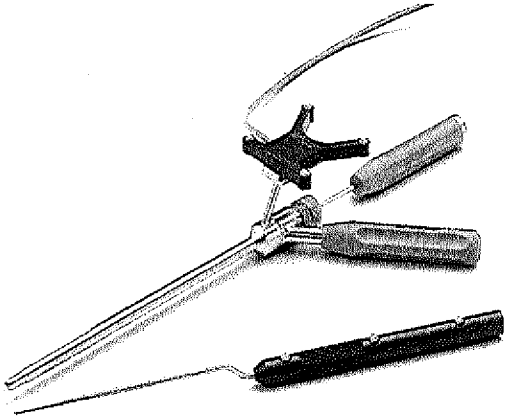
Date: 10-21-2008

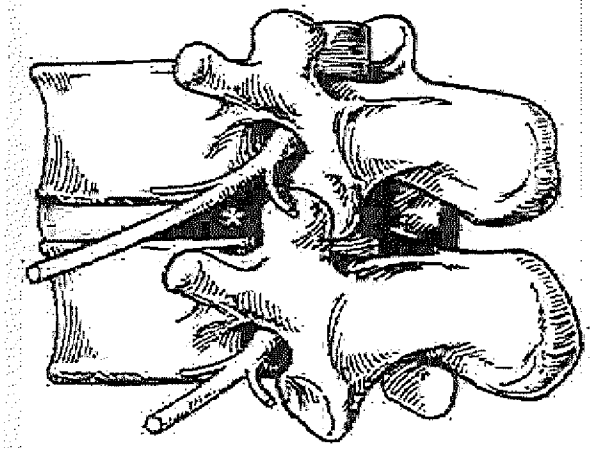
Lawrence M. Boyd

Minimally Invasive Surgical Approach

- Inject scaffold + robust engineered cells with matrix into disc space
- Image-guided placement of guide wire into triangular working zone for disc access

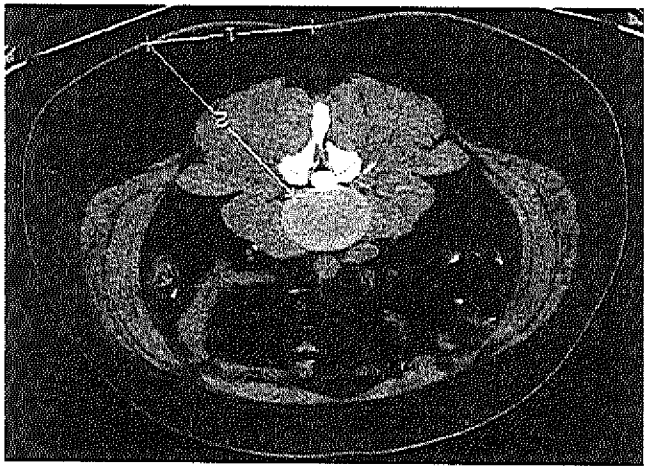


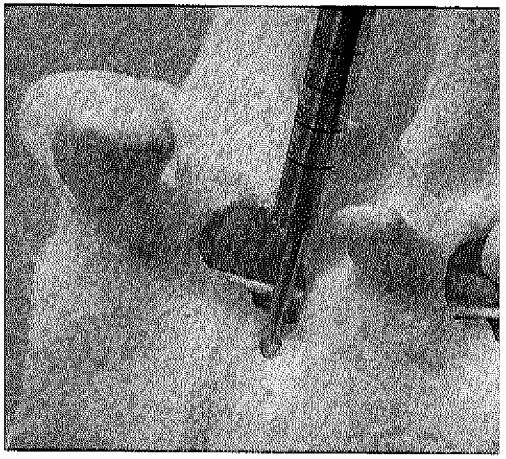


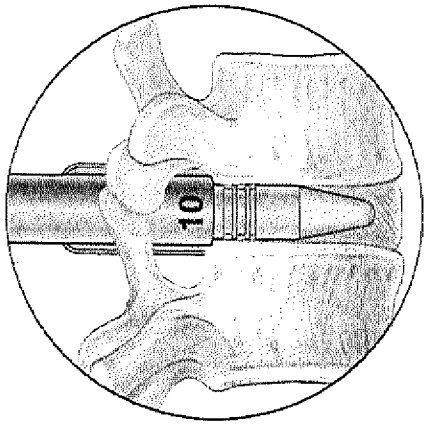


Surgical Technique – Spinal Access

- Following image guided wire placement, trephine for anular opening, multiple trephines if needed to remove disc material
- Distractor to restore disc height and maintain during injection and polymerization of biomaterial







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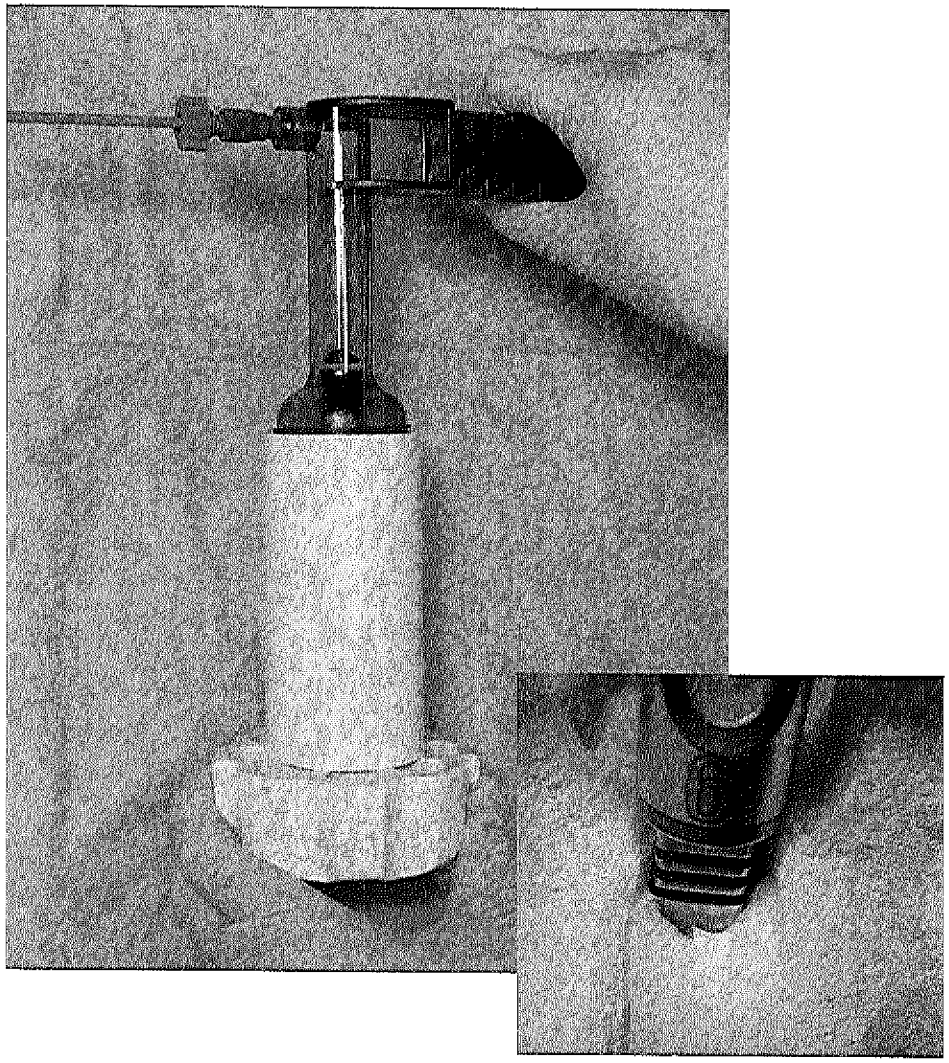
Surgical Technique – Biomaterial Injection

- Load biomaterial + chondrocytes into injection device
- Injection down cannulated distractor to maintain height during polymerization



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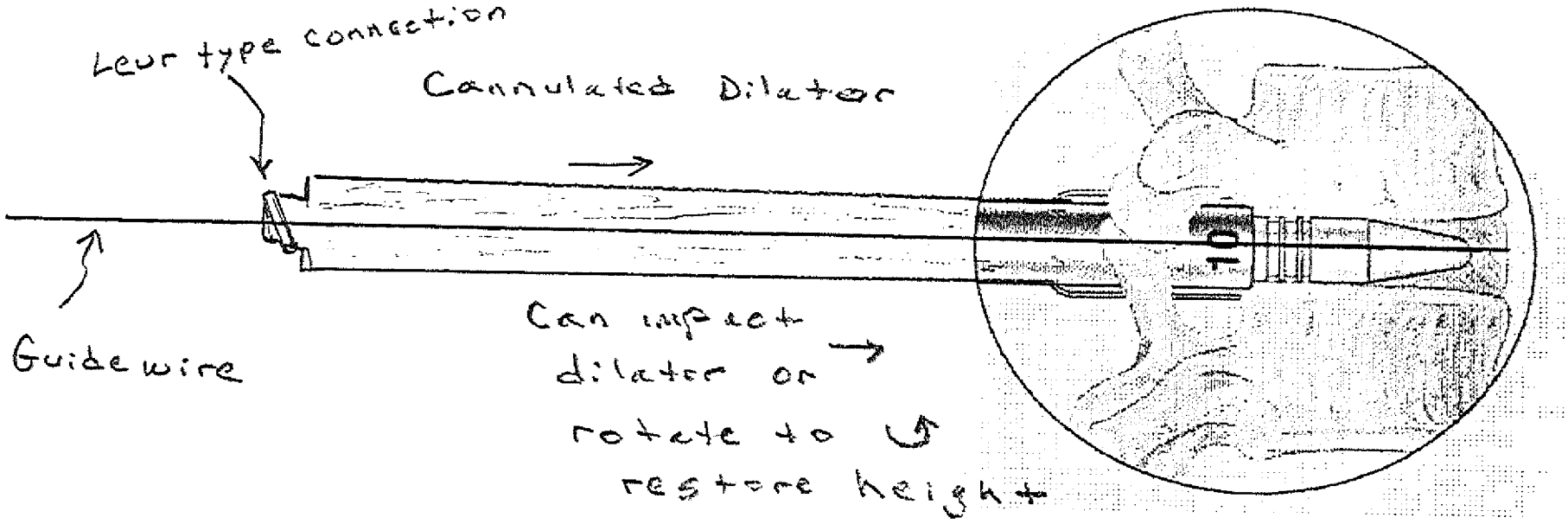
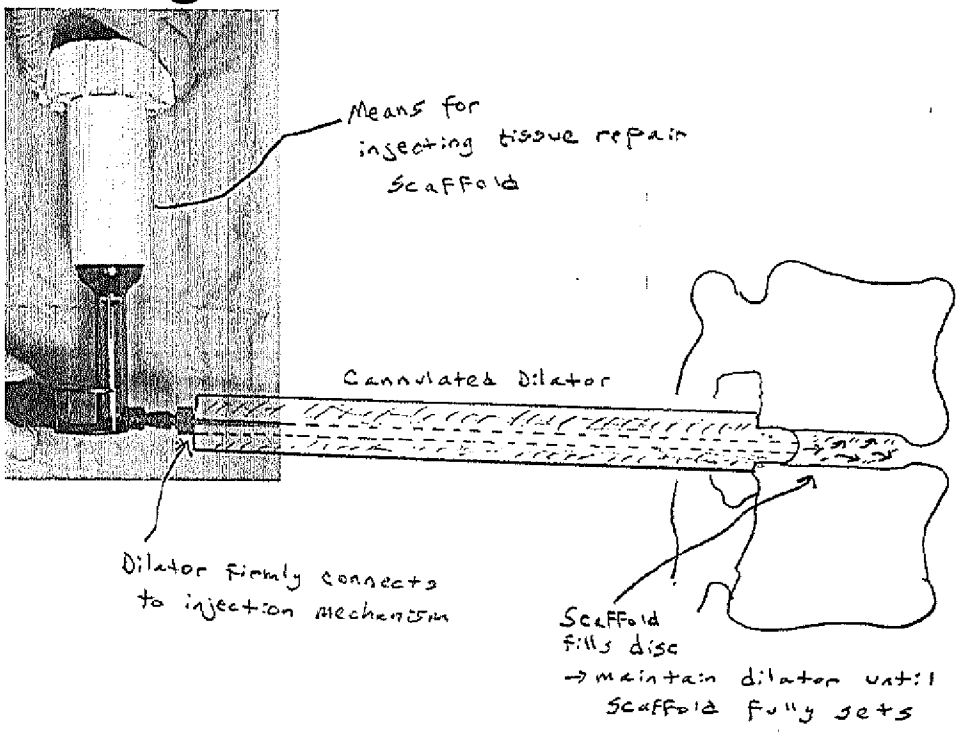
Distractor/Injection Cannula

- Cannulated dilator restores and maintains disc height during biomaterial set time



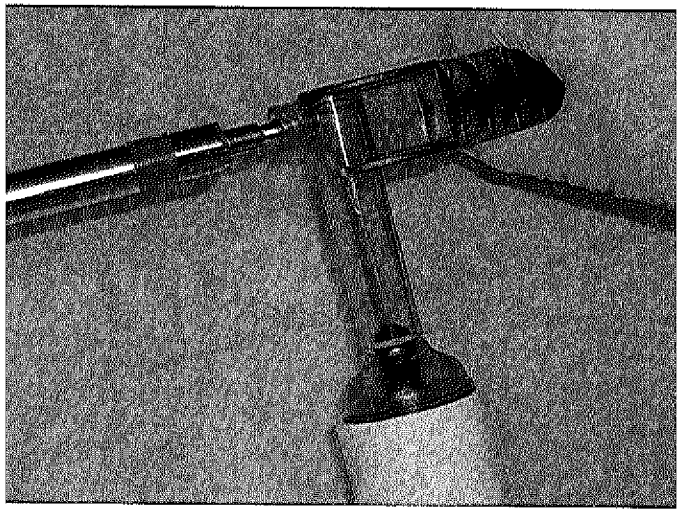
Distractor/Injection Cannula

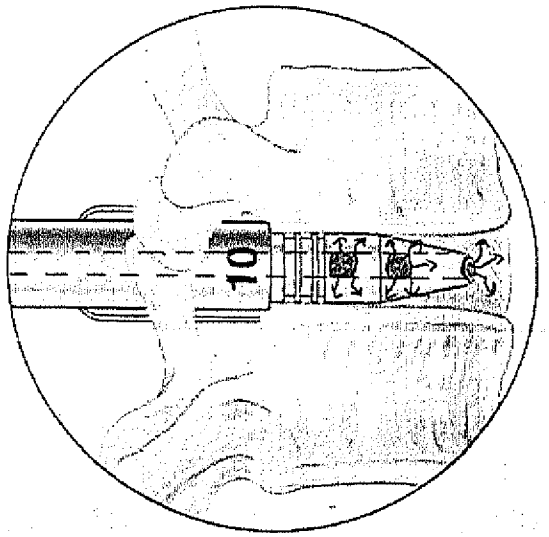
- Fluid delivery mechanism attached to proximal end locking mechanism
- Access may also be used for placement of light cable if photocured or fluid components for crosslinking



Distractor/Injection Cannula

- Dilator tip directs fluid distally and medially for complete filling of disc space
- Dilator tip may be radiolucent plastic for enhanced imaging
- Dilator tip may be detachable and resorbable polymer if long set time needed





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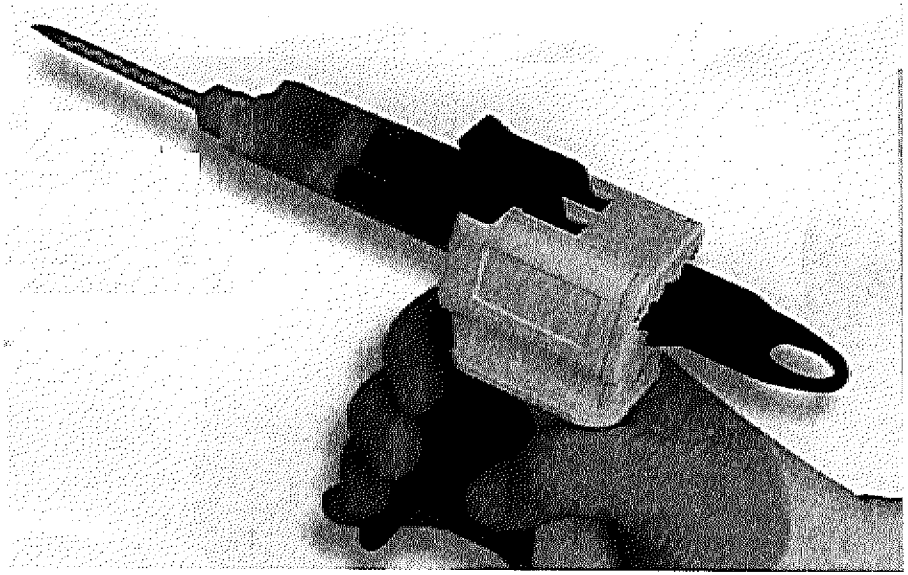
Anular Repair Options

- Photopolymerizable seal, i.e. *FocalSeal,* Focal Inc., Lexington, MA
  - Tested in animal studies (White *et al.,* 2000)
- Fibrin glue as an alternative option
  - Clinical trials (Petsas *et al.,*1995)



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Michael D. Beck
Baker & Daniels
600 East 96th Street
Suite 600
Indianapolis, IN 46240-3728

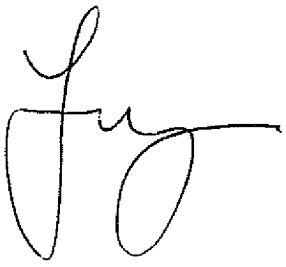
Confidential
Attorney-Client

Dear Mike,

Enclosed please find two sets of documents related to the two concepts upon which I would like you to file provisional applications. The first document is the primary disclosure and focuses simply on describing concepts 1 and 2. The second set of documents is a copy of part of a presentation that I gave at on the concepts. I hope that these two documents will allow you to file the provisional patent applications.

My primary aim in filing these provisional applications is to clearly define my ownership of these two concepts so that I can present them to SpineWave for their consideration. I hope these documents are sufficient without the need for a great deal of work on your part. Please look these over and call or e-mail me to discuss the next steps. I will look forward to hearing from you.

Yours Sincerely,



Concept 1 – A method and instruments for injection of a biomaterial for repair and regeneration of the intervertebral disc

An injectable material is most ideal of repair and/or regeneration of the degenerated intervertebral disc. There are many solid biomaterials being pursued for articular cartilage repair like porous scaffolds of various polymers (e.g., PLA, PGA) or natural materials such as collagen. Use of these solid scaffolds in the intervertebral disc will require a relatively open procedure for their implantation and they will never precisely conform to all the anatomical features of the intradiscal space. However, there are also many materials now under investigation that can be injected into the disc space like hyaluronic acid, fibrin glue, alginate, elastin-like polypeptide, collagen type I gel, and others. There are many references and some good general reviews on the subject of injectable biomaterials.

These injectable materials allow for disc repair via a minimally invasive approach to the disc. Many methods are available for cannula-based access to the disc and for image-guided direction of the surgical instruments into the disc space. The biomaterials used for repair are injected in a fluid state and then undergo some form of crosslinking or phase transformation into a more solid state suitable for withstanding the loading requirements of the spine. For example, photoinitiators can be added to allow for application of a light source to initiate cross-linking. A phase transformation may occur at increased temperature of the body. In all these cases, it is necessary to maintain the disc space (height and volume) while the polymer system undergoes a transformation into a state capable of maintaining the restored anatomical relationships.

Figures 1 to 5A (attached) document the methodology used to repair the disc via an injectable biomaterial.

The procedure involves placement of a guidewire (Figure 1) in a commonly known manner, but could with today's technology easily be adapted to placement using image guidance The disc is normally accessed via the triangular working zone bordered by the exiting nerve root, dura and superior endplate of the inferior vertebrae. The placement of guidewires to access a degenerated disc involves an anatomical pathway such as that shown in Figure 2.

The next step involves use of trephine to penetrate the outer annulus (Figure 3) and to access the disc nucleus pulposus for the reparative procedure. The trephine follows the previously placed guidewire. If necessary, sequential trephines of increasing sizes may be used to remove some of the nuclear material prior to distraction of the vertebral bodies in the next step.

One novelty of this proposed procedure is the use of a cannulated distractor to now follow the guidewire into the disc space and to restore disc height prior to injection of the biomaterial (Figure 4). The distractor is cannulated and can restore disc height via direct

impaction of a bullet-shaped leading end or via a wedge shape that can be rotated 90 degrees to wedge open the vertebrae. The proximal end of the distractor features a locking mechanism for easy and secure connection to the fluid-delivery mechanism in the next step.

The dilator remains in the disc space maintaining the restored intradiscal space and anatomical allignment. The guidewire is removed and a fluid-delivery mechanism is attached to the end of the dilator. The injectable biomaterial is now delivered into the disc space (Figure 5). The dilator remains in place while the biomaterial achieves the appropriate degree of solidity for maintenance of disc height. The cannulated dilator could also be used as an access means for placement of a light cable if the material requires light for photocuring or for other access to facilitate crosslinking or transformation of the biomaterial.

The dilator tip may feature a variety of openings to facilitate filling of the disc space and uniform and complete dispersion of the biomaterial into the disc for repair and regeneration (Figure 5A). Additionally, this dilator tip may be radiolucent in order to not obscure radiographic imaging of the injection of the biomaterial (which will likely feature some radiodense attributes for visualization). Also, this dilator tip may be fabricated from a resorbable biomaterial (e.g., PLLA, PGA, etc.) and detached in order to leave behind the structure to maintain height for a longer period of time. This would allow the surgeon to close the patient, letting the biomaterial undergo transformation for a longer time period and facilitating healing in an unloaded condition prior to degradation of the tip and restoration of normal loading.

Novelty – This concept represents a unique view on the use of the dilator or distractors typically used to restore disc height and spinal anatomy during interbody fusion procedures. I am not currently aware of anyone proposing the use of the dilator as a means of delivering an injectable biomaterial and maintaining the space during biomaterial crosslinking for disc repair procedures..

From: Larry Boyd <lmb13@acpub.duke.edu>
To: <mdbeck@bakerd.com>
Date:
Subject: Fwd: Re: Article of Interest

Mike,
See below. I will try to give you a call later today to discuss this. I need to clean up my disclosure some before I think it is in a good position for a provisional. My thoughts have been that it makes sense to have you file the provisional for me, since I am hopeful that SpineWave will be interested in picking this up and filing the full application at a later time. Talk with you soon. Larry.

From: Larry Boyd <lmb13@acpub.duke.edu>
To: "Michael Beck" <MDBECK@bakerd.com>
Date:
Subject: Re: Provisional app

Mike,
Here are our comments on this provisional. They are not extensive, but I do want to make it clear that the concept of leaving the resorbable dilator behind is only one option. It seems likely that many of these materials will have relatively quick set times and the surgeon can just leave the instrument in place in the OR for a brief period before removing them and closing the patient.

Here is Maureen's Address information:

Maureen Upton
1805 White Pine Drive
Durham, North Carolina 27705

I will look forward to seeing the signature documents and moving ahead with this. Thanks for your efforts. Looks good. Regards, Larry.

0, you wrote:
>Larry:
> Attached is the first provisional. The figures are the same that you
> provided except with Fig. 5A renumber to Fig. 6. The second provisional
> will follow in another e-mail.
>
> We are mailing the appropriate signature papers for both cases.
>
>michael
>
>
>Michael D. Beck
>317-569-4668
>317-569-4800 (general fax)
>317-237-8468 (direct fax)
>mdbeck@bakerd.com
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>
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WASHINGTON, D.C.
QINGDAO, P.R. CHINA

Mr. Lawrence M. Boyd
25 Birnham Lane
Durham, NC 27707

Re: U.S. Provisional Application
Title: DEVICES, ASSEMBLIES AND METHODS FOR INTERVERTEBRAL DISC REPAIR AND REGENERATION.
Our Ref.: Boyd-02

Dear Larry:

I am enclosing a copy of the above Provisional Patent Application for final review by you and Maureen. Let me know if the application needs further revisions.

Please sign and date the enclosed Declaration and Power of Attorney where indicated and return to me in the enclosed self-addressed envelope.

If you have any questions regarding the Provisional Application or the execution of the Declaration, please do not hesitate to contact me.

Sincerely,

Michael D. Beck

MDB/slb
Enclosures